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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/675,254

09/30/2003

Hikaru Matsuda

49288.0800

2567

7590

07/19/2006

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EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/675,254

Applicant(s)

MATSUDA ET AL.

Examiner

David L. Vanik

Art Unit

1615

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 11 July 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 1-4 and 6-17.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
13. ☐ Other: _____.

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1506

7/14/06

Continuation of 11. does NOT place the application in condition for allowance because: The Applicant's claim amendments and arguments have been carefully considered. However, after considering Applicant's assertions, the examiner respectfully maintains the 35 U.S.C. 103 rejections and submits that the instant claim amendments do not place the application in condition for allowance. Specifically, as set forth in the 5/12/2006 Final Rejection, '618 teach a method delivering the active agents at a predetermined rate that may include acceleration/deceleration patterns (column 8, lines 45-54). Depending on the type of syringe used, the flow rate and needle exit velocity can be varied (column 6, lines 14-42). For example, when a 30 gauge needle is used (an inner diameter of 0.25 mm - See US 6,273,715; column 4, lines 59-67), the flow rate is 0.12 ml/s or 7.2 ml/minute (Table 1). Thus, '618 teach a method of injecting an active agent at a predetermined rate between about 1 ml/min to 20 ml/min. '618 also teaches that a multitude of active agents, such as insulin, pharmaceutical agents, and vitamins, are suitable for use with the injection method. Again, as set forth in the 5/12/2006 Final Rejection, '604 provide motivation for injecting cell-based pharmaceuticals into the heart of a subject. Because muscle cells, when injected into a heart, can advantageously aid in cardiac repair, one of ordinary skill in the art would have been motivated to inject cardiac cells into a heart in a manner consistent with the disclosure of '618. Based on the teachings of '604, there is a reasonable expectation cardiac cells, when injected into a heart, can aid in cardiac repair. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to inject cells, in a manner consistent with the method advanced by '618, into a heart.

Barring a showing of unexpected results, the examiner respectfully submits that the above rejection meets the claim limitations of the instant amended claim set. Additionally, after carefully considering Applicant's remarks, the examiner respectfully submits that the 35 U.S.C. 103 rejection over '624 in view of '604 still stands for the reasons set forth in the 5/12/2006 Final Rejection.